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Percutaneous versus open cannulation for mechanical support in patients with right ventricular failure after left ventricular assist device placement

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Abstract

Aim: Temporary right ventricular assist device (t-RVAD) is an option for those patients in right ventricular failure (RVF) after left ventricular assist device (LVAD) resistant to ionotropic therapy. There are two options to placing a t-RVAD: an open, central technique or a percutaneous placement with Protek Duo® cannula.

Methods: We compare these two t-RVAD devices that treat RVF after LVAD placement. Between 2013–2019, 22 patients were identified needing t-RVAD support after LVAD placement. Fourteen patients had open/central while 8 patients had percutaneous right ventricular assist device (RVAD) support.

Results: There was no difference in length of ICU stay (49 ± 32 days Protek Duo® vs. 45 ± 22 days "open"; $P = 0.73$); hospital length of stay (57 ± 39 days vs. 55 ± 28 days; $P = 0.088$); discharge from ICU and hospital (62.1% Protek Duo® vs. 57% for "open"; $P = 0.9$ for both); or the one-year survival between the two groups (62% Protek Duo® vs. 50% "open"; $P = 0.67$). The Protek Duo® group had less total time on the ventilator (15 ± 9 days vs. 27 ± 17 days; $P = 0.044$) and required less amount of blood products (17 ± 8.9 units RBC and 2.0 ± 1.91 units FFP vs. 31 ± 20.5 units RBC and 11.5 ± 10 units FFP; $P = 0.046$ and $P = 0.005$).

Conclusions: Percutaneous t-RVAD support is a viable option for patients whom undergo LVAD placement and require right ventricular mechanical support.

Keywords

Mechanical circulatory support, RV failure, RVAD support, LVAD, cardiac surgery

Introduction

As patients with end-stage heart failure are living longer and increasing in numbers; left ventricular assist devices (LVADs) are becoming more common as a therapeutic treatment option when conventional medical therapy has reached its limit. These devices are being used as either a bridge to transplant or as destination

therapy. Many patients with advanced heart failure that require LVAD support have some degree of right ventricular (RV) dysfunction. It is estimated that RV failure (RVF) occurs in approximately 10–40% of LVAD recipients [1–3]. Aggressive treatment of this RV failure is paramount to a successful outcome after LVAD implantation.

Severe RVF is manifested by an increase in central venous pressure (CVP), hepatic, and renal dysfunction, and low LVAD flows due to decreased preload for the device [4]. This is associated with increased peri-operative mortality, prolonged hospital stay, and poor quality of life [5, 6]. Treatment of RVF includes inotropes, nitric oxide (NO), and mechanical support. Continued high dose inotropes can lead to bowel and limb ischemia along with increasing myocardial oxygen demand [7]. RVF that continues to worsen despite high dose ionotropic medical therapy may require a RV assist device (RVAD).

There are two types of temporary RVAD (t-RVAD) devices. The first is placed in the operating room through an open sternotomy where blood is drained from the right atrium and returned into the pulmonary artery (PA) through cannulas placed directly in the right atrium and the PA [7]. This type of approach requires reoperation an additional sternotomy when the t-RVAD needs to be explanted after RV recovery (Figure 1). Another t-RVAD is a Protek Duo® cannula (Figure 2): a dual lumen single cannula that is percutaneously inserted into the right internal jugular vein and is advanced under fluoroscopy or direct visualization into the PA [8]. The advantage of this percutaneous t-RVAD is that it can be removed at the bedside and does not require reoperation or repeat sternotomy. The purpose of this study is to determine in those patients with refractory RVF that require RV mechanical support after LVAD implantation; how does the new percutaneous Protek Duo® RVAD device compare to the traditional "open" t-RVAD which requires an additional sternotomy for removal.

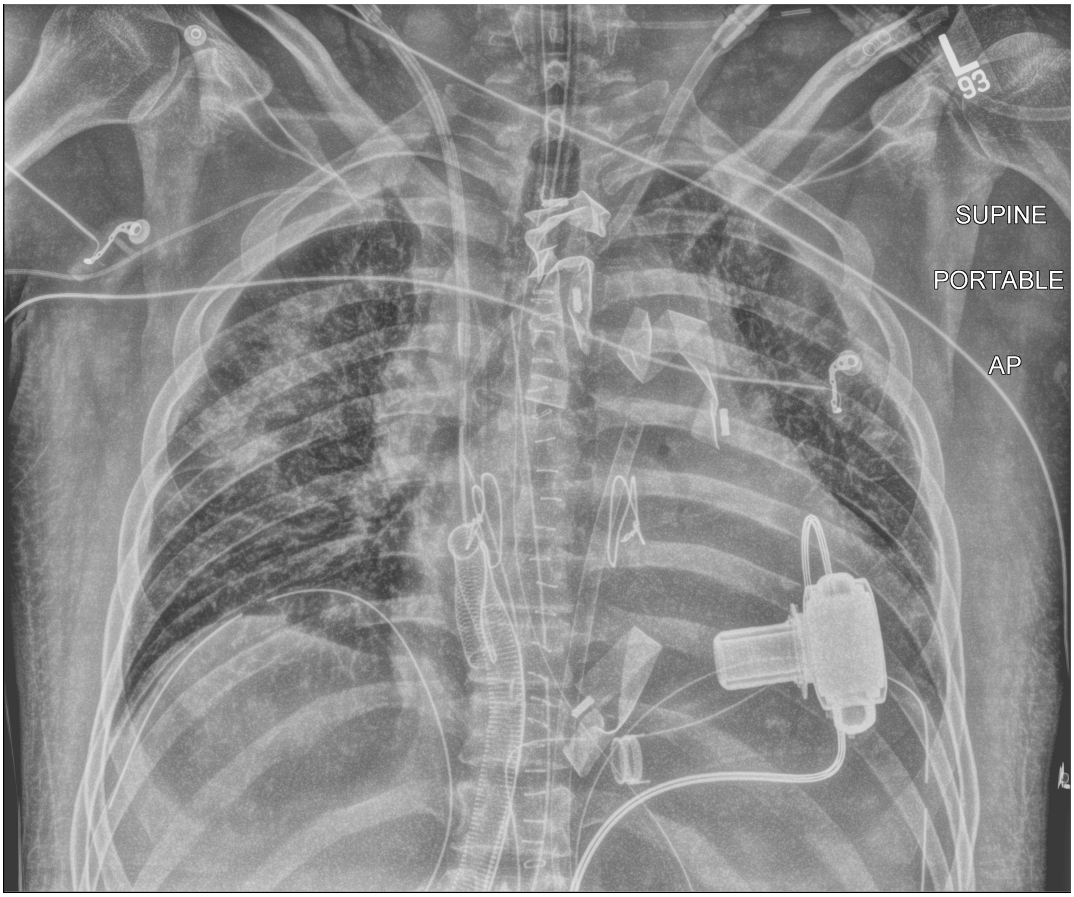

Figure 1. Open RVAD placement in the operating room after HeartWare LVAD implantation. RVAD: right ventricular assist device; LVAD: left ventricular assist device

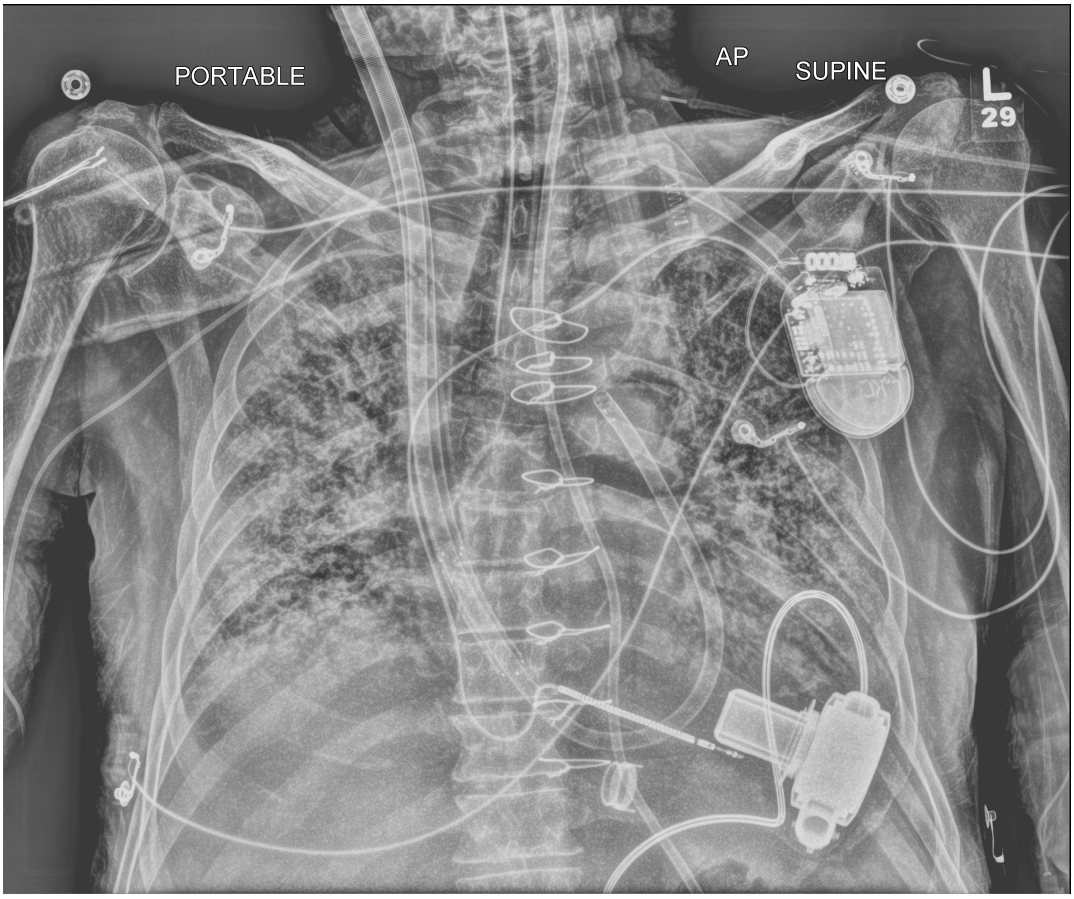

Figure 2. Percutaneous RVAD placement with Protek Duo® in the operating room after HeartWare LVAD implantation. RVAD: right ventricular assist device; LVAD: left ventricular assist device

Materials and methods

This was a retrospective, single center, observational study. After Institutional Review Board approval, we identified 28 patients between 2013–2019 that required a t-RVAD device after LVAD implantation. The LVAD patients were identified by using a master list of all LVAD patients implanted at our institution that was kept by the LVAD coordinators in the cardiology heart failure department. We then sub-divided those patients that had the diagnosis of RVF. We then further subdivided those RVF patients to those who received t-RVAD support by using the billing code of veno-venous extracorporeal membrane oxygenation (VV-ECMO); as these patients were billed for VV-ECMO management as they all had an oxygenator on the t-RVAD device. Inclusion criteria included: Age > 18 years, primary LVAD implantation, and t-RVAD after LVAD implantation. Exclusion criteria included second LVAD implantation and late implantation of t-RVAD, which was identified as greater than 72 h for placement of RVAD after the initial LVAD operation. This excluded 6 patients from our analysis as t-RVAD support was placed greater than 72 h after LVAD implantation. The primary endpoint was one-year survival. Secondary endpoints were evidence of cardiac tamponade, other bleeding, requirement of blood products (red blood cells, fresh frozen plasma, and platelets), need for and duration of NO therapy, duration of t-RVAD support, renal replacement therapy (and duration), duration of mechanical ventilation, liver dysfunction, need for and duration of vasopressors, discharge alive from the intensive care unit (ICU), ICU length of stay, hospital length of stay, and the need for heart transplantation.

The 22 t-RVAD patients were placed into two groups: RVAD with a percutaneously placed Protek Duo® cannula or "open" t-RVAD—which was placed through open sternotomy and required a return to operating room for removal. A total of 8 patients were identified requiring Protek Duo® support and 14 patients required "open" RVAD support after new LVAD implantation (Figure 3).

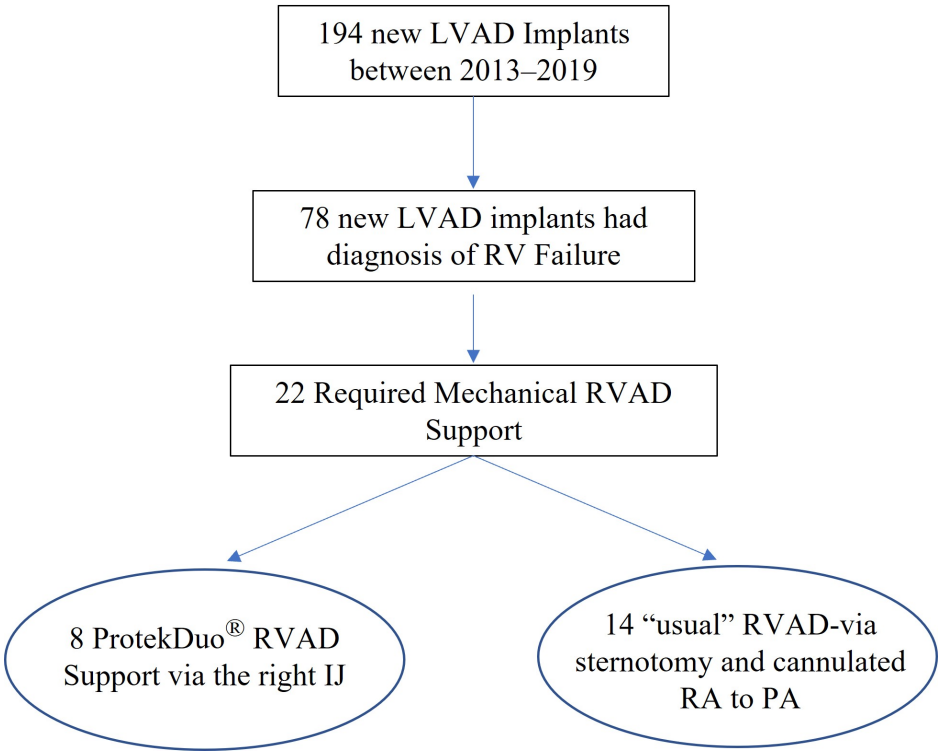

Figure 3. Flow chart of LVAD implantations requiring RVAD support. LVAD: left ventricular assist device; RVAD: right ventricular assist device; RV: right ventricle; IJ: internal jugular; RA: right atrium; PA: pulmonary artery

Determination for LVAD placement

Patient selection for LVAD implantation was determined by an interdisciplinary team, which consisted of cardiac surgery, advanced heart failure cardiology, social work, pharmacy, cardiac intensive care team and LVAD coordinators. The International Society of Heart and Lung Transplantation recommendations [8] for permanent mechanical circulatory support standards were followed. The type of LVAD placed was determined by cardiac surgery.

Determination of need of RVAD

The need of t-RVAD support after cardiopulmonary bypass in the operating room was determined by the attending cardiothoracic surgeon and attending cardiothoracic. LVAD placement was placed by the same surgeon in every case, and t-RVAD support was initiated when the patient was maximized on two inotropes and goal flow on the LVAD was not achieved. This was confirmed with Swan-Ganz catheter which confirmed a cardiac index < 2.2 and by transesophageal echo. The type of t-RVAD support, Protek Duo® vs. "open", was determined and placed by cardiac surgery. The need t-RVAD after leaving the operating room was determined by the cardiothoracic surgeon, intensive care team, and advanced heart failure cardiologists. The same criteria were used in the ICU as in the operating room to trigger the for need of t-RVAD support; which was usually the patient maximized on inotropic support without reaching goal flow on the LVAD device confirmed by Swan-Ganz catheter. If a Protek Duo® t-RVAD support device was decided as the method for RVAD support, this was placed by interventional cardiology under fluoroscopy in the cardiac catherization lab.

Statistics

Continuous variables were expressed as median [interquartile range (IQR)] or mean ± standard deviation, depending on distribution, and were compared using Mann-Whitney test or Student's *T*-test, as appropriate. We checked the linearity of continuous variables using fractional polynomial regression, and we dichotomized non-linear continuous variables based on the median. Categorical variables were reported as frequencies and percentages, and were compared using the chi-square test. Analysis was performed with alpha risk of 5%. The analyses were performed using STATA software, version 15.1 (Lakeway Drive, TX).

Results

Patient baseline characteristics on day of LVAD implantation

Twenty-two patients were included in this analysis, with mean age of 55.7 and mean LVEF of 17.1%, of which over half were male. A total of 8 patients required Protek Duo® RVAD support and 14 patients required the "open" RVAD support after LVAD implantation for advanced heart failure. The mean age for the Protek Duo® group was 54 years old with half being male and for the "open" group the mean age was 56 years old with 57% being male. Approximately two-thirds of patients in the Protek Duo® group were INTERMACS stage 1 while almost all of the "open" group were INTERMACS 1. Of the Protek Duo® group, only one-quarter had immediate RVAD implantation while almost all of the "open" group had immediate RVAD implantation intraoperatively. In the Protek Duo® group around two-thirds had implantation of RVAD support more than 48 h after LVAD implantation while this only occurred in in less than 10% of the "open" group. In the Protek Duo® group, most had a HeartWare LVAD implanted; while the "open" RVAD group had a more even distribution of implantation between HeartWare and HeartMate II. Both groups P:F ratios excluded acute respiratory distress syndrome as a diagnosis.

Clinical Data 48 h after LVAD implant

There was no difference in mean arterial pressure (MVP) or CVP between the Protek Duo® group and "open" group after LVAD implantation. However, the Protek Duo® group had more patients on mechanical ventilation compared to the "open" group. Furthermore, there was more thrombocytopenia in the "open" group but this could be explained because majority of the Protek Duo® group had a delay in t-RVAD support while the "open" group which had t-RVAD immediately placed in the operating room leading to faster extubation.

Short-term outcomes

There was no difference in the one-year survival between the two groups. There was also no statistical difference in ICU length of stay or hospital length of stay. Furthermore, there was no difference for both discharge from ICU and discharge alive from the hospital. However, the Protek Duo® group had significantly less total time on mechanical ventilation, and required less blood products.

Discussion

RV failure is the most common complication after implantation of a left ventricular assist device. High dose inotropes and vasopressors may be necessary to help the right ventricle to provide enough preload for the LVAD achieve goal flow. However, high dose inotropes after cardiac surgery has been associated with many complications including limb and bowel ischemia. In order to limit this complication from high inotropes, a RV assist device may be used. The classic method of "open" cannulation is achieved by placing two cannulas—one in the right atrium and other in the PA after cardiotomy and LVAD placement. The downside to this is re-sternotomy is required for t-RVAD explanation. The other is now a percutaneous dual lumen single cannula that is placed in the right internal jugular vein to the PA. This is known as the Protek Duo® cannula [4, 9–11], which can be removed at bedside after RV recovery.

In this retrospective analysis of outcomes following temporary RVAD (t-RVAD) implantation, "open" vs. Protek Duo® RVAD, 22 patients, with mean age of 55.7 and mean LVEF of 17.1%, met the inclusion criteria. Baseline characteristics amongst the two groups were similar aside from albumin level and PaO_2/FiO_2 ratio, which were both higher in the Protek Duo® group (Table 1). Even though it was not statistically significant, all most all "open" RVAD patients were INTERMACS 1. There was also a difference in timing of RVAD implantation: most "open" t-RVADs were implanted immediately after cardiac bypass in the operating, versus only a quarter in the Protek Duo® group. Consequently, in the Protek Duo® group more than half of the RVAD implantations occurred between 48–72 h; where as in the "open" t-RVAD group there was only 1 case of delayed RVAD implantation (Table 1). In both groups, 48 h after LVAD implantation the hemodynamics and vasopressor use were similar, however the "open" t-RVAD group had lower platelet count and greater need for mechanical ventilation (Table 2). The average time on t-RVAD support was

similar between both groups. There were significant differences in the total number of days of mechanical ventilation and the Protek Duo® group had overall less use of blood products. There was also no difference in MVP as the goal was to keep it between 60–70 mmHg to reduce the influence of afterload that could be impairing the LVAD function. Also, the CVP for both groups was elevated above normal to ensure adequate preload was given to the RV to help with function. There were no differences in ICU length of stay, discharge alive from the ICU, hospital length of stay, or one-year survival (Table 3).

Table 1. Baseline characteristics of patients before left ventricular assist device implantation

Parameters	RVAD with Protek Duo® cannula *N* = 8	Open t-RVAD *N* = 14	*P*
Age	54.5 ± 14.1	56.3 ± 9.7	0.77
Sex (Male)	4 (50)	8 (57.1)	0.76
BMI	30.8 ± 6.5	33.0 ± 8.3	0.52
History of hypertension	2 (25)	10 (71.4)	0.14
History of tobacco	4 (50)	6 (42.9)	0.9
Ischemic cardiomyopathy	5 (62.5)	11 (78.6)	0.62
EF before the implantation	19 ± 6	16 ± 5	0.07
INTERMACS stage 1	5 (62.5)	13 (92.9)	0.12
Creatinine (mg/dL)	1.54 ± 0.60	1.38 ± 0.58	0.58
Bilirubin (mg/dL)	9 ± 13.8	11.0 ± 9.8	0.72
AST (unit/L)	157 ± 162	62 ± 36	0.61
Platelets (k/uL)	186 ± 79	140 ± 107	0.27
Lactate (mmol/L)	3 ± 2.7	4.8 ± 4.7	0.61
Albumin (g/dL)	**3.4 ± 0.40**	**2.96 ± 0.39**	**< 0.001**
MAP (mmHg)	59 ± 11	65 ± 7	0.20
CVP (mmHg)	20 ± 5	15 ± 7	0.09
Mechanical ventilation the day before the LVAD implantation	1 (12.5)	7 (50)	0.16
$Pa0_2/Fi0_2$ ratio before LVAD	**257 ± 133**	**235 ± 110**	**0.001**
CRRT	5 (62.5)	9 (64.3)	0.9
Short-term devices before LVAD			
VA-ECMO	5 (62.5)	11 (78.6)	0.47
Impella®	1 (12.5)	4 (28.60)	
Both	1 (12.5)	1(7.1)	
Type of LVAD			
Heart Ware	7 (87.5)	6(42.9)	0.07
HeartMate II	1 (12.5)	8 (57.1)	
Oxygenator with RVAD [Y/N]	8 (100)	13 (92.9)	0.9
Immediate RVAD implantation	**2 (25)**	**12 (85.7)**	**0.008**
Delay implantation between LVAD and RVAD > 48 h	**5 (62.5)**	**1 (7.1)**	**0.01**

RVAD: right ventricular assist device; BMI: body mass index; EF: ejection fraction; MAP: mean arterial pressure; CVP: central venous pressure; LVAD: left ventricular assist device: CRRT: continuous renal replacement therapy; VA-ECMO: veno-venous extracorporeal membrane oxygenation; AST: aspartate aminotransferase. Statistically significant differences are bolded and highlighted

Table 2. Clinical, hemodynamic, and biological parameters 48 h after RVAD implantation

Parameters	RVAD with Protek Duo® cannula *N* = 8	Open t-RVAD *N* = 14	*P*-value
Hemodynamic data			
MAP (mmHg)	63 ± 6	57 ± 5	0.05
CVP (mmHg)	17 ± 2	20 ± 7	0.09
Biological data			
Creatinine (mg/dL)	1.29 ± 0.38	1.42 ± 0.74	0.61

Table 2. Clinical, hemodynamic, and biological parameters 48 h after RVAD implantation (*continued*)

Parameters	RVAD with Protek Duo® cannula *N* = 8	Open t-RVAD *N* = 14	*P*-value
Bilirubin (mg/dL)	9 ± 13	6 ± 4	0.75
AST (unit/L)	892 ± 815	346 ± 794	2.09
Lactate (mmol/L)	2.0 ± 0.4	4.8 ± 4.6	0.05
Platelets (k/uL)	**180 ± 91**	**99 ± 40**	**0.049**
Life supports			
Use of NO	8 (100)	8 (57.1)	0.05
Requiring mechanical ventilation > 24 h	**7 (87.5)**	**11 (78.6)**	**0.04**
Use of renal replacement therapy	5 (62.5)	9 (64.3)	0.92
Epinephrine doses 24 h after the RVAD (mcg/kg/min)	0.05 ± 0.04	0.05 ± 0.06	0.85
Norepinephrine doses 24 h after the RVAD (mcg/kg/min)	0.02 ± 0.035	0.02 ± 0.035	0.82
Milrinone doses 24 h after the RVAD (mcg/kg/min)	0.23 ± 0.22	0.12 ± 0.19	0.21
Vasopressin doses 24 h after the RVAD (u/hour)	0.04 ± 0.037	0.29 ± 0.035	0.59

RVAD: right ventricular assist device; MAP: mean arterial pressure; CVP: central venous pressure; AST: aspartate aminotransferase; NO: nitric oxide; RVAD: right ventricular assist device. Statistically significant differences are bolded and highlighted

Table 3. Short-term outcomes based on type of temporary right ventricular assist device used

Parameters	RVAD with Protek Duo® cannula *N* = 8	Open t-RVAD *N* = 14	*P*
Number of days under RVAD	15.6 ± 5.8	15.1 ± 14.2	0.91
Use of renal replacement therapy	5 (62.5)	9 (64.3)	0.92
Number of days under renal replacement therapy	32.6 ± 53.8	22.1 ± 24.5	0.61
Number of days under mechanical ventilation	**15 ± 9**	**27 ± 17**	**0.044**
Use of post-LVAD NO	8 (100)	8 (57.1)	0.05
Number of hours under NO	63 ± 44	110 ± 203	0.41
Number of days under vasopressors	40 ± 28	38 ± 26	0.82
Complications			
Bleeding	7 (87.5)	12 (85.7)	0.98
Tamponade	6 (75)	10 (71.4)	0.9
Cannulation site bleeding	1 (12.5)	0	0.36
Other major bleeding	1 (12.5)	0	0.36
Thrombocytopenia (< 50 G/L)	5 (62.5)	13 (92.9)	0.12
Number of units of red blood cells	**17 ± 8.9**	**31 ± 20.5**	**0.046**
Number of units of FFP	**2.0 ± 1.91**	**11.5 ± 10.0**	**0.005**
Number of doses of platelets	4 ± 5	5 ± 3.1	0.66
Stroke	1 (12.5)	2 (7.1)	0.9
Causes of death			
MOF	1 (12.5)	2 (14.2)	0.9
Sepsis	0	1 (7.1)	0.9
Stroke	1 (12.5)	2 (14.2)	0.9
Uncontrolled bleeding	0	1 (7.1)	0.9
Pump dysfunction	1 (12.5)	0	0.9
Other	0	0	
Withholding or withdrawing life-sustaining treatment	3 (37.5)	5 (35.7)	0.90
Discharge alive from ICU	5 (62.5)	8 (57.1)	0.90
ICU length of stay	49 ± 32	45 ± 22	0.73
Discharge alive from hospital	5 (62.5)	8 (57.1)	0.90
Hospital length of stay	57 ± 39	55 ± 28	0.88
One-year survival	5 (62.5)	7 (50)	0.67

RVAD: right ventricular assist device; LVAD: left ventricular assist device; NO: nitric oxide: FFP: fresh frozen plasma: MOF: multi-organ failure: ICU: intensive care unit. Statistically significant differences are bolded and highlighted

There was no difference in long term outcomes when RVAD was implanted immediately (more likely with "open" t-RVADs) or in the delayed strategy (implantation > 48 h post LVAD, more common in the Protek Duo® group). This suggest that use of a Protek Duo® as strategy for refractory RV failure is a viable option, and a short-term trial of high dose inotropes could be used to help with RV recovery without immediate mechanical support. Because the Protek Duo® is a less invasive method of RV support, there should hypothetically be less complications. This was captured in this study by the use of far less use of blood products in the Protek Duo® group, even in the setting of an equal chance of bleeding events between the two groups. This observation may have been driven by the fact that the "open" t-RVAD requires repeat sternotomy for RVAD explanation; whereas Protek Duo® removal is a bedside procedure. Based on these findings, a viable strategy for RV failure after LVAD implantation could allow for use of high dose inotropes for 48 h and if no RV recovery is observed, a Protek Duo® could be placed percutaneously for long term mechanical RV support.

We determined that there was no decrease in effectiveness in RV support by using the Protek Duo® vs. "open" t-RVAD, as seen by no difference in long term outcomes (ICU/hospital length of stay and one-year survival) as well as amount of vasopressor/inotropic/NO use post-RVAD implantation. Average days under mechanical ventilation was greater in the "open" t-RVAD group, but this cohort also had a lower PaO_2/FiO_2 ratio on day of LVAD implantation. One major advantage of the Protek Duo® cannula is that it can be taken out at bedside; thus, there is no need for a reoperation for removal. This leads to less bleeding and infection risk, and allows for earlier extubation in the ICU after the operation. The delay in placement of the Protek Duo® with no difference in outcome allow clinicians to try to manage the RV failure medically after LVAD placement, and to determine if mechanical RV support is absolutely necessary. This will lessen the need for mechanical right heart support, which can increase risk of bleeding and infection no matter which method of t-RVAD strategy is utilized. [10, 11–15].

Limitations

There are several limitations to this study. First, this is a retrospective study with a relatively small number of patients. Second, the type of LVAD device used and the type of t-RVAD used was determined by the cardiac surgeon in the operating room or in the ICU and was not standardized to any protocol. Third, the trigger to place the t-RVAD device was subjective and based on the clinical judgement of the providers taking care of the patients. This usually was when the patient was maximized on two inotropes and achieving LVAD flows less than goal—confirmed by Swan-Ganz catheter—but it may not be the case in every patient. Finally, the "open" cannulation t-RVAD group, even though not statistically significant, were more critically ill preoperatively as almost all their patients were classified as INTERMACS 1.

Conclusions

The Protek Duo® percutaneous right internal jugular to PA RV support catheter is a viable option for patients whom undergo LVAD placement and require mechanical support for RV failure.

Abbreviations

CVP: central venous pressure

ICU: intensive care unit

LVAD: left ventricular assist device

MAP: mean arterial pressure

NO: nitric oxide

PA: pulmonary artery

RV: right ventricular

RVAD: right ventricular assist device

RVF: right ventricular failure

t-RVAD: temporary right ventricular assist device

VV-ECMO: veno-venous extracorporeal membrane oxygenation

Declarations

Author contributions

AP: Writing—original draft. AK: Data curation. NA: Data curation, Formal Analysis. CB: Writing—original draft. BS: Writing—review & editing.

Conflicts of interest

The authors declare that they have no conflicts of interest.

Ethical approval

This study was approved by the institutional review board at Penn State Health: Study identification number: STUDY00012511.

Consent to participate

During the institutional review board (IRB) application, the need for consent was waived as there were no unique patient identifiers that would be used in the data of this project.

Consent to publication

Not applicable.

Availability of data and materials

The datasets generated in this study can be found with the corresponding author and the raw data can be available if requested.

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Not applicable.

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